

Basic Standard: IEC 60601-1-2

Essential Performance, Risk Analysis and Immunity Testing

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When the second edition of Basic Standard: IEC/EN 60601-1-2 became the mandatory EMC standard for medical devices on November 1st, 2004 the EMC landscape for medical electrical equipment was changed forever. Although EMC immunity test requirements for medical products are very similar to those applied to other product types, such as radio equipment, networking equipment, and information technology equipment, Basic Standard: IEC 60601-1-2 requires that the performance criteria address all essential functions of the medical device. [Table 1]

Essential functions may be determined from a risk analysis. The outcome of this analysis should identify the performance associated with each function of the device that is “necessary to maintain the residual risk within acceptable limits.” [1]

It may not be possible to assess multiple functions simultaneously therefore each test may need to be repeated. Without the risk analysis, all functions are considered to be essential so a risk analysis is necessary to minimize the amount of testing required.

Having determined the functions, and their associated parameters, that need to be evaluated during immunity tests, the next step is to develop a test plan that addresses how each function will be evaluated, identify those functions that can be evaluated simultaneously and provide the cycle time for each of these functions.

The cycle time for each of the functions to be evaluated can have a very significant impact on the sweep rates for the radiated and conducted immunity tests because the standard requires that the dwell time at each

Electro-static Discharge (ESD)	Basic Standard: IEC1000-4-2 Test Level(s): ±8kV Air / ±6kV Contact
Radiated Immunity	Basic Standard: IEC 1000-4-3 Frequency Range: 80 - 2500MHz Test Level(s): 3V/m (10V/m for life support equipment) Modulation: 1kHz (2Hz for equipment that monitors physiological parameters) 80% AM
Fast Transients	Basic Standard: IEC 1000-4-4 Test Level(s): AC ports: ±2kV; Signal ports that connect to cables longer than 3m ±1kV to be tested with EUT operating from both maximum and minimum voltages. Patient coupled cables are not to be tested.
Surge	Basic Standard: IEC 1000-4-5 Test Level(s): AC ports: 2kV CM, 1kV DM, CM = Common Mode (line to ground), DM = Differential Mode (line to line), To be tested with EUT operating from both maximum and minimum voltages
Conducted Immunity	Basic Standard: IEC 61000-4-6 Frequency Range: 0.15 – 80 MHz Test Level(s): 3V (10V for life support equipment) Modulation: 1kHz (2Hz for equipment that monitors physiological parameters) 80% AM, Applies to all AC, DC, patient and interface ports
Power Frequency Magnetic Fields	Basic Standard: IEC 1000-4-8 Test Level(s): 50Hz and 60Hz @ 3A/m

Table 1: Immunity Tests Required by EN/Basic Standard: IEC 60601-1-2 Edition 2

frequency step is 1.2 times the sampling period. For example, if a device processes data by taking multiple samples and averaging them and then providing a result every 60 seconds the dwell time at each frequency step would be 72 seconds.

Both radiated and conducted immunity tests use a frequency step size of 1% and a typical sweep rate of 1.5×10^{-3} decades/s. Table 2 shows the number of steps in the frequency ranges for both conducted immunity (0.12 – 80 MHz) and radiated immunity (80 – 2500 MHz) and compares the total test time for a nominal sweep rate of 1.5×10^{-3} decade/s (~2.9 seconds per frequency) versus a sweep rate requiring 60 seconds per frequency. [Table 2]

The test times for conducted immunity in the table above are compounded by the number of interface cables, with the test typically applied to each interface cable in turn.

For radiated immunity the device is typically tested four times (each side of the device facing the transmitting antenna) sides, but portable devices should be tested on all six sides). Each side is tested twice, once with the transmitting antenna vertically polarized and once with the antenna horizontally polarized. A portable device, therefore, would be tested a total of 12 times.

For transient immunity tests, the issue of cycle time can also have an impact on test times since the application of the transient cannot be synchronized to the “most susceptible” operating cycle of the device. Depending on the function/process being evaluated, the test may need to be applied over multiple cycles.

If the risk analysis has been done ahead of time, it may be possible to implement test modes in advance of

testing that use fewer samples (thereby reducing the cycle time of the device) or allow multiple functions to be monitored simultaneously. It must be noted that test modes have to be fully representative of the real-world application, so it may not always be possible to implement test-time-reducing features and meet the requirements of the Notified Body or Government Agency responsible for reviewing your test data.

Some examples of systems we have tested, the definition of essential performance and its impact on the test plan follow.

Case #1: Infusion Pump

Infusion pumps have their own, product specific standard Basic Standard: IEC/EN 60601-2-24. Although this standard makes some modifications to the requirements of Basic Standard: IEC/EN 60601-1-2 the essential performance, risk analysis and their effects on the EMC immunity test plan are representative of issues for all medical devices.

The essential performance of the pump was identified as providing fluid at a flow rate that remained within tolerance (the tolerance was defined based on technical judgment from within the manufacturer’s expertise in this specific medical application). In addition, the pumps ability to detect certain error conditions (such as air in the line or line occlusions) and create an alarm was also considered a part of essential performance. This meant that two modes had to be tested – normal mode (with the pump infusing at a pre-determined rate) and alarm mode (with various types of errors introduced into the system).

To address the flow-rate evaluation the manufacturer first considered the use of a scale to determine the volume infused over a certain period of time. This method was considered inappropriate because short

Start Frequency (MHz)	Stop Frequency (MHz)	Steps	Total test time per sweep 1.5×10^{-3} decade/s	Total test time per sweep 72 s per step
0.15	80	632	30 minutes	759 minutes, (12.7 hours)
80	2500	347	17 minutes	416 minutes, (6.9 hours)

Times in the table above do not account for any test equipment settling times or leveling times, which add overhead. This overhead is typically independent of the dwell time per frequency step.

Table 2: Test Times for Radiated and Conducted Immunity

duration changes in the instantaneous flow rate might go unnoticed when the weight of fluid delivered was averaged over the duration of a test. To counter this, the manufacturer developed an additional device to measure flow rate and to give a visual indication if the flow rate went out of tolerance. The flow meter had to be tested for immunity prior to performing the test to determine any susceptibilities prior to testing the final product to ensure any flow-rate alarms were because of the device susceptibility and not the monitoring equipment.

The alarm conduction tests required no special test equipment since the error conditions could be recreated by manually injecting air into the line or pinching off the fluid line. As these conditions could not be recreated on a continuous basis, the manufacturer followed our recommendations to run these tests at spot frequencies for radiated and conducted immunity, with the frequencies selected based on the operating frequencies of ISM and radio devices in the hospital environment. For transient tests (ESD, surge, voltage dips and interruptions), as the transient phenomena are all short duration events and the error condition would be a long duration event, the primary concern was that these transients did not damage the error-detection circuitry or inhibit the alarm. The ability to detect the error conditions was verified before and after applying each phenomena, while also verifying that the transient phenomena did not reset the alarm condition.

Prior to implementing the above test plan there was some discussion on the possibility of having a method of monitoring the alarm circuitry during “normal” operation to verify that they were not susceptible to the applied phenomena (for example, by indication of the analog output from the circuit). This was not possible on the current product line but may be implemented into future products. While it may not alleviate testing in the alarm mode, it might reduce the number of tests required by allowing selection of reduced tests on the mode based on the areas where the circuits showed susceptibility.

Case #2: Telemetry System

This device contained a sensor and would periodically send data acquired by the sensor to a remote data

logging device. In normal operation the device would transmit every 2 minutes, however the interval could be adjusted for the device to transmit every 90 seconds. It was not possible to reduce this sampling time any further because the device required this as a minimum sampling time to avoid producing invalid data.

Although no complicated test configuration issues with this device, the fact that the dwell time could be reduced from 144 seconds (if the cycle time had been 120 seconds) to 108 seconds (for a cycle time of 90 seconds) represented a test time saving of almost twenty-eight hours for radiated immunity.

Cycle Time (seconds)	90	120
Dwell Time (seconds)	108	144
Test Time per side (minutes)	625	833
Total Test Time (hours)	83	111
Dwell time equals 1.2 times cycle time. Test time per side based on 347 frequency steps from 80 MHz to 2500 MHz. Total test time is for four sides, 2 polarizations		

Table 3: Time Savings – 90 second versus 120 second dwell time

This case also brought up the issue of exclusion bands for testing. In effect, the standards allow for some degradation in performance within an exclusion band around the operating frequency of the device under test, if the device is a receiver of rf EM energy. The exclusion band is defined in section 2.211 of IEC 60601-1-2 as the

“...frequency band for intentional receivers of RF electromagnetic energy that extends from -5 % to +5 % of the frequency, or frequency band, of reception for frequencies of reception greater than or equal to 80 MHz and from -10 % to +10 % of the frequency, or frequency band, of reception for frequencies of reception less than 80 MHz”

Within these bands, the 60601-1-2 standard allows exemptions from the essential performance requirements, although it should be noted that the device under test is required to remain safe, and the exemption only applies to the receiver functions of the device. To accommodate the exclusion bands, the test software

for radiated and conducted immunity was modified to skip over the exclusion band when evaluating the receive functions.

The application of the exclusion band brought up an interesting internal discussion within our EMC group regarding the use of exclusion bands for critical functions, especially when the interference signal could be present for a significant duration. Our own conclusion was that a life-critical function should not rely on an unlicensed rf communication link prone to interference.

Case #3: Ablation System

This piece of medical equipment is designed to use rf heating to cauterize during surgical procedures. The risk analysis resulted in identifying two possible problems that might result in an unacceptable safety risk during operation – the first was if the power setting should change or if the device should power-on unintentionally. It was determined that the rf switching off unintentionally was not a risk provided that the instrument indicated that the rf was off and did not re-initiate without manual control.

Two test modes were, therefore, tested. The first was with the power set at a midpoint to allow the displayed power to be monitored for an unacceptable increase or decrease. The second mode was with the device operating in a stand-by mode to ensure that it did not switch on the rf unintentionally. By providing two samples, radiated immunity was performed on both modes simultaneously to reduce test time.

Case #4: Home Use Patient Monitoring System

The risk analysis for this product concluded that there were no functions that were considered essential to the safety of the patient. Any information obtained by the

system would be evaluated on a case-by-case basis, and the system was to be used to provide additional patient information between out-patient visits to the physician. Any abnormal data recorded by the system would be evaluated by a physician who, in turn, would run additional tests before making a diagnosis and prescribing treatment.

In this case, the requirements state that it is not necessary to perform immunity tests to declare compliance. However, the manufacturer still wanted to know if their product was susceptible, so testing was performed. The performance criteria were not related to essential performance, but to anticipated customer expectations.

Summary

Hopefully the importance of performing a risk analysis has been highlighted by this article. Product-specific knowledge and, in many cases, medical expertise are required to make an effective risk analysis that clearly identifies the essential performance and minimizes the number of functions and parameters that need to be evaluated for susceptibility to the EMC phenomena outlined in the second edition of IEC/EN 60601-1-2. The EMC test lab should be able to provide guidance in implementing a test plan based on the essential performance parameters and functions identified by the risk analysis.

1. *Basic Standard: IEC 60601-1-2 Edition 2, section 2.210*

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